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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application : **Group Art Unit:** 1617
Shoji Uchiyama and Kenji Haramaki :
Serial Number: 09/933,989 : **Examiner:** Jennifer M. Kim
:
Filed: August 20, 2001 : **Attn. Docket No.:** Y02YL017
:
Title: Use of Agaricus Blazei Murill to : **Date:** October 29, 2003
Prevent or Treat Skin and Other Disorders :
:
:

Mail Stop Art Unit 1617
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Sir:

Responsive to the Office Action mailed June 30, 2003 which is due July 30, 2003, please enter the following election and remarks.

A Petition for Extension of Time (of three (3) months), along with a check for the appropriate fee, is enclosed with this Response. If any other fees are necessary, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Omori & Yaguchi USA, LLC deposit account no. 502270.

The previous attorney(s) in this case inadvertently made an error by failing to certify Applicant/Owner as a Small Entity. We hereby certify that Applicant/Owner has Small Entity status, and the appropriate Small Entity fee for the Petition for Extension of Time is submitted herewith.

The Examiner states that claims 46-49 are generic to a plurality of disclosed patentably distinct species comprising disorders. The Examiner requires, under 35 U.S.C. 121, the election of a single disclosed species. The Examiner considers claims 46-49 as a Markush group.

Pursuant to 37 C.F.R. 1.143, Applicant elects the autoimmune disorder of rheumatoid arthritis, as included in claim 49.

However, Applicant respectfully traverses this restriction requirement. According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 to § 806.05(i)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) to § 806.04(i), § 808.01(a), and § 808.02).

For purposes of the initial requirement, a serious burden may be prima facie shown if the examiner shows separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02.

In the subject application, all of the claimed disorders at issue are autoimmune diseases. As described in the specification at page 9, lines 2-21, autoimmune disease occurs when the immune system mistakenly attacks the self, targeting the cells, tissues, and organs of a person's own body. There are many different autoimmune diseases, and they can each affect the body in different ways.

The present claims 46-49 at issue claim some examples of autoimmune disease, including some well known ones such as rheumatoid arthritis and multiple sclerosis. In medical and scientific terms, these diseases are often collectively grouped under the general umbrella of "autoimmune diseases". Indeed, many of these disorders may have the same or analogous mechanisms of action. Obviously, current research in the art focuses on the immune system, and physicians and scientists have so far identified more than 80 such disorders.


Thus, Applicant respectfully submits that these disorders would not typically have separate classifications or separate statuses in the art, and that they do not generally reside in different fields of search. Applicant believes that the claimed disorders at issue would generally belong within the same classifications, such as specific classifications belonging to Class 514 (drug, bio-affecting and body treating compositions). Therefore, a search related to the prevention and treatment of such specific fourteen (14) autoimmune disorders at issue should not pose a serious burden on the Examiner.

Applicant respectfully argues that, under the above cited sections of the MPEP and the current state of the art, a restriction requirement among these autoimmune disorders is not warranted. These disorders usually have the same status of belonging to the general "autoimmune disease" group in the art, and a search of methods to prevent and treat such disorders would not pose a serious burden on the Examiner, as they would typically be classified in the same or related classes.

Thus, Applicant respectfully requests the withdrawal of the restriction requirement, as criteria (B) above, as stated in the MPEP, is not satisfied for warranting a proper restriction requirement.

If the Examiner believes the prosecution of this application would be advanced by a telephone call, the Examiner is invited to contact Applicant's attorney at the telephone number indicated below.

Respectfully submitted,

By: 
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